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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/642,591 | 08/19/2003 | Takaaki Isshiki | 0020-5166P | 2938 |

2292 7590 03/14/2007
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| EXAMINER |
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THALER, MICHAEL H

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| ART UNIT | PAPER NUMBER |
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3731

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|--|-------------------|---------------|
| 3 MONTHS | 03/14/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/14/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/642,591

Applicant(s)

ISSHIKI ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "filed thereto said inner and outer rings" in line 4 is unclear and is not understood.

Claims 1, 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116). Khosravi discloses sheath 52 being closed at the proximal end (by the narrow proximal region described in col. 5, lines 19-25), a flexible shaft (the combination of shaft 12 and member 54 which is attached thereto as indicated in col. 5, lines 32-35, and noting that shaft 12 is flexible in the embodiment described in col. 4, lines 13-16 due to the articulations therein), thrombus capture member 14, 16 comprising a plurality of wires 24 forming a frame and having a configuration swollen in the middle portion and mounted slidably on shaft 12 at the distal end but fixed on the shaft at the proximal end thereof (col. 4, lines 24-27). Khosravi fails to disclose the filter frame wires 24 as being spiral and crossed with one another. However, Brooks et al. teach that filter frame wires 56 for supporting an endovascular filter membrane should be spiral and crossed with one another (col. 4, lines 37-43) apparently in order to obtain the advantage of better

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supporting the filter membrane around its circumference. It would have been obvious to make the Khosravi filter frame wires 24 spiral and crossed with one another so that it too would have this advantage. As to claim 4, Khosravi fails to disclose a hemostatic valve. However, it is old and well known to use hemostatic valve in surgical devices in order to obtain the advantage of preventing blood loss. It would have been obvious to include a hemostatic valve in the Khosravi device so that it too would have this advantage. The proximal portion of shaft 12 of Khosravi protrudes from the sheath 52 when the shaft 12 is inserted therein as described in col. 5, lines 51-56. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). As to claim 7, as best understood, Khosravi fails to disclose the slide ring assembly as comprising an inner ring and an outer ring with the wires sandwiched therebetween. However, it is old and well known in this art to secure wires between inner and outer rings in order to obtain the advantage of providing a strong attachment between the wires and ring assembly. It would have been obvious to so construct the sliding ring in the Khosravi device so that it too would have this advantage.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116) as applied to claim 1 above, and further in view of Rosenbluth (WO 99/56801). As to claim 5, Khosravi fails to disclose a side hole and second lumen in the sheath. However, Rosenbluth teaches that a sheath 11''' for an intravascular filter should include a side hole 310 and second lumen 309 in order to obtain the advantage of permitting rapid exchange of the sheath (page 18, lines 13-22). It would have been obvious to include a side hole and second lumen in the Khosravi sheath so that it too would have this advantage. As to claim 6, Khosravi fails to disclose a side infusion tube. However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side infusion port 15 attached thereto in order to obtain the advantage of permitting injection of contrast medium into the vessel (page 15, lines 15-24). It would have been obvious to include a side infusion port in the Khosravi device so that it too would have this advantage.

Applicant's arguments filed Dec. 27, 2006 have been fully considered but they are not persuasive. The allegation on page 8 of the remarks that Brooks et al. fail to disclose struts or helical members crossed with one another is incorrect. The embodiment described in col. 4, lines 37-43 clearly includes

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helical members crossed with one another since the members are described as being braided (i.e. with a dense braid on the distal portion and a less dense braid on the proximal portion) and are shown in figure 4 as being helical. Braided members, by definition, cross one another.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571) 272-4704. The examiner can normally be reached Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

mht



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731